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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,142	09/24/2003	George R. Greene JR.	612-04-CIP3-CON	7335

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EXAMINER	
SWIGER III, JAMES L	
ART UNIT	**PAPER NUMBER**
3733	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/670,142	GREENE ET AL.	
	Examiner	Art Unit	
	James L. Swiger	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-35,56-59,61,62 and 64-71* is/are pending in the application.

4a) Of the above claim(s) *29,30 and 62-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27,28,31-35,56-59,61 and 68-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/24/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-28, 57-58, and 68-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Zollikofer et al. ("A Combination of Stainless Steel Coil...").

Zollikofer et al. disclose an embolic device comprising a flexible filamentous carrier along a length of wire (see Fig. 4a). Because of its coiled shape, the wire is capable of elastic memory, being initially configured in a formed loop structure and is expandible as a continuous length of microcoil that would form a 3-D shape. Zollikofer et al. also disclose embolizing elements that are formed of an expansible hydrophilic polymer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zollikofer et al. in view of Phelps et al. (US Patent 5,382,259). Zollikofer et al. disclose the claimed invention *supra* except for the embolizing element to be partially made of stretch-resistant material. Phelps et al. disclose an embolization device comprising a flexible filamentous carrier having a continuous coaxial embolizing element non-releasibly fixed to the exterior surface along a substantial portion of the carrier. The embolizing elements are formed of a stretch-resistant biocompatible polymer (e.g. a polyester or nylon). See Col. 2, lines 50-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Zollikofer et al. having at least a material that is stretch-resistant in view of Phelps et al. to better use the device.

Claims 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zollikofer et al. in view of Palermo et al. (US Patent 5,350,397). Zollikofer discloses the claimed invention except for a linkage element. Palermo et al. teaches to provide a proximal end of a carrier with a linkage element that releasable attaches to the carrier, such as to a distal end of a deployment instrument (see Col. 1, lines 6-14). This is done so that the positioning of the coil at the site may be controlled to a fine degree of accuracy (see Col. 2, lines 1-6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Zollikofer et al. with a linkage element in view of Palermo et al. to better control to a fine degree of accuracy the position of the device in use.

Claims 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over

the combination of Zollikofer et al. and Palermo et al. '397 as applied to claim 31 above, and further in view of Rosenbluth et al. (US Patent 6,015,424).

The combination of Zollikofer et al. and Palermo et al. '397 disclose the claimed invention except for deployment of the linkage element by electric, heat or fluid pressure. Rosenbluth et al. teaches the use of electric current (see Col. 8, lines 10-20), heat (see Col. 2, lines 35-47), and pressure (Col 4, lines 30-37). These variations allow for an improved deployment of the linkage element and embolic device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Zollikofer et al. and Palermo et al. '397 having at least the use of electricity, heat, and or fluid pressure to better deploy the instrument in use.

Claims 59 and 61 rejected under 35 U.S.C. 103(a) as being unpatentable over Zollikofer et al. in view of Evans et al. (US patent 5,695,480). Zollikofer et al. disclose the claimed invention except for the embolizing element being radiopaque. Evans et al. disclose that the embolizing elements can have radiopaque agents in order that the physician can visualize the delivery of the embolizing elements to the vascular site via convention techniques, such as fluoroscopy (see Col2, lines 15-19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Zollikofer et al. with the embolizing elements having radiopaque agents in view of Evans et al. in order to allow the physician to visualize the delivery of the embolizing elements.

Claim 60 rejected under 35 U.S.C. 103(a) as being unpatentable over Zollikofer et al. Zollikofer et al. disclose the claimed invention except for the embolizing element made of a material selected from a group consisting of polyvinyl alcohol and pHEMA. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the embolizing element out of this material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed 1/31/2007 have been fully considered but they are not persuasive. According to the applicant's specification, the purpose of the embolic device is to occlude a body cavity by expanding and filling the space so that it does not create a problem such as a blood clot. With respect to the art, polyvinyl alcohol (PA) is a substance that is capable of expanding in the presence of an aqueous environment. It is considered a polymer, or at least considered an ethanol homopolymer. What exactly is considered "volumentrically controlled" or "exhibiting a delayed volumetric expansion" is inherent in the function of the material. If in the preparation of the prior art device occurs with minor dehydration in an acidic presence, it will expand in the body as the pH raises closes to that of blood, which is a basic presence in the typical range of 7.35-7.5. Variations in the conditions of the blood may cause a variations in expansion. For example, blood that is more basic will have a greater pH gradient and will most likely cause the PA in the device to expand faster than a pH closer to neutral. Conversely, the

carrier device may have had other acidic or preliminary treatments to affect its volumetric expansion.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

4/15/2007

JLS

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER